UNITED STATES DISTRICT COURT EASTERN DISTRICT OF VIRGINIA NORFOLK DIVISION

IN RE: ZETIA (EZETIMIBE) ANTITRUST LITIGATION

MDL No. 2:18-md-2836

THIS DOCUMENT RELATES TO: ALL DIRECT PURCHASER CLASS ACTIONS

DIRECT PURCHASER PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION FOR CLASS CERTIFICATION FOR PURPOSES OF SETTLEMENT WITH PAR PHARMACEUTICAL, INC., APPOINTMENT OF CLASS COUNSEL, PRELIMINARY APPROVAL OF PROPOSED SETTLEMENT, APPROVAL OF THE FORM AND MANNER OF NOTICE TO THE CLASS, APPOINTMENT OF A NOTICE ADMINISTRATOR, A STAY OF ALL PROCEEDINGS IN THE MDL AS AGAINST PAR, AND SETTING THE FINAL SETTLEMENT SCHEDULE AND DATE FOR A FAIRNESS HEARING

I. INTRODUCTION¹

Direct Purchaser Class Plaintiffs,² on behalf of the proposed class of direct purchasers, have entered into a proposed settlement with defendant Par Pharmaceutical, Inc. ("Par").³ The Settlement provides that Par will produce agreed-upon discovery, including documents, data, and deposition testimony (and testimony at trial if necessary) in the ongoing litigation on an expedited basis. Par also covenants not to bring or assert claims or counterclaims against the remaining defendants, Merck or Glenmark,⁴ arising under the Sherman or Clayton Acts relating to the conduct alleged in Direct Purchaser Class Plaintiffs' Complaint.⁵ In exchange, the Direct Purchaser Class Plaintiffs will dismiss this case with prejudice as to defendant Par only, provide a release from Direct Purchaser Class Plaintiffs and the Direct Purchaser Class (as defined below), and seek a stay of all proceedings in this MDL as against Par in the interim.⁶

The Settlement is the result of good faith, arms-length negotiation following a thorough investigation by class counsel for the Direct Purchaser Class Plaintiffs. Par denies any allegations of unlawful or wrongful conduct, and believes they have meritorious defenses to this litigation.

¹ Tables of Contents and Authorities are appended hereto as Appendices A and B, respectively.

² Direct Purchaser Class Plaintiffs include: FWK Holdings, LLC, Rochester Drug Co-Operative, Inc., and Cesar Castillo, Inc.

³ See Exhibits 1 and 2 to the Declaration of Thomas M. Sobol ("Sobol Decl. Ex.") submitted herewith (Par Settlement Agreement and Modification to Settlement Agreement). The proposed settlement, along with the Modification to Settlement Agreement are referred to together herein as the "Settlement."

⁴ "Merck" refers to Merck & Co., Inc., Merck Sharp & Dohme Corp., Schering-Plough Corp., Schering Corp., and MSP Singapore Co. LLC. "Glenmark" refers to Glenmark Pharmaceuticals, Ltd. and Glenmark Generics Inc., USA ("Glenmark"). Merck, Glenmark, and Par are referred to collectively herein as "Defendants."

⁵ References to the "Complaint" are to the Direct Purchaser Plaintiffs' Amended Consolidated Class Action Complaint (ECF No. 315). Unless otherwise specified, all ECF references are to those in this multi-district litigation.

⁶ Par does not oppose preliminary approval of the settlement.

Thus, the Settlement ensures that the Direct Purchaser Settlement Class will receive substantial benefit from the Settlement in the form of expedited, discovery, witness availability for trial, and a covenant by Par, a purchaser of generic Zetia, not to sue Merck or Glenmark for antitrust violations, while avoiding the uncertainties and delays of continued litigation against Par, or the uncertainties associated with Par's financial condition, including the collectability of any judgment against the company. Interim Lead Class Counsel for Direct Purchaser Class Plaintiffs⁷ believe that the Settlement is fair and reasonable and satisfy the requirements of Fed. R. Civ. P. 23(e). The Settlement therefore meets the standards for preliminary approval.

Accordingly, Direct Purchaser Class Plaintiffs respectfully request that the Court enter an order substantially in the form of the proposed Preliminary Approval Order submitted herewith, (1) granting Direct Purchaser Class Plaintiffs' motion for certification of the Direct Purchaser Settlement Class under Fed. R. Civ. P. 23 for purposes of settlement with Par; (2) granting preliminary approval of the proposed Settlement with Par; (3) approving the proposed form and manner of notice to the Direct Purchaser Settlement Class, including appointment of a notice administrator, and adopting a proposed schedule; (4) designating Hagens Berman Sobol Shapiro LLP as Lead Class Counsel; (5) staying all proceedings against Par in the MDL pending final approval of the Settlement; and (6) scheduling a date for a Fairness Hearing.⁸

⁷ On August 15, 2018, the Court appointed Hagens Berman Sobol Shapiro LLP as Interim Co-Lead Class Counsel for the proposed class of direct purchasers. ECF No. 115.

⁸ See [Proposed] Order submitted herewith, Sobol Decl., Ex. 3.

II. BACKGROUND

A. Direct Purchaser Class Plaintiffs allege the defendants violated federal antitrust law, imposing overcharges on the Direct Purchaser Class.

This is an antitrust class action brought on behalf of a proposed class of direct purchasers of the prescription drug Zetia or its generic equivalent.

Beginning in January 2018, Direct Purchaser Class Plaintiffs filed multiple lawsuits against Glenmark and Merck),⁹ alleging those entities had entered into an unlawful "reverse payment" settlement agreement, delaying entry of generic substitutes from the market for ezetimibe, a prescription cholesterol drug, sold under the brand name Zetia by Merck for years. On July 3, 2018, these actions, including all related actions later filed, were coordinated in the Zetia Antitrust MDL.

On May 8, 2019, the Direct Purchaser Class Plaintiffs sough leave to file an Amended Consolidated Class Action Complaint, adding Par as a defendant, inter alia. On June 21, 2019, the Direct Purchaser Class Plaintiffs and Par entered into the proposed Settlement. On June 25, 2019, after holding a hearing the day before, the Court granted the motion for leave to amend. The Direct Purchaser Class Plaintiffs filed their Amended Complaint on June 27, 2019.

B. The proposed Settlement comes after months of investigation and discovery into Par's involvement in the alleged anticompetitive scheme, and arms-length settlement negotiations.

Par entered into a distribution arrangement with Glenmark in which Par agreed to serve as the exclusive distributor of Glenmark's generic Zetia, ¹³ and Par performed under the terms of

⁹ The Direct Purchaser cases include: *FWK Holdings, LLC v. Merck & Co., Inc.*, 2:18-cv-00023 (E.D. Va.); *Cesar Castillo, Inc. v. Merck & Co., Inc.*, 2:18-cv-00039 (E.D. Va.); and *Rochester Drug Cooperative, Inc. v. Merck & Co., Inc.*, 2:18-cv-00071 (E.D. Va.).

¹⁰ ECF Nos. 249, 250, 250-1.

¹¹ Sobol Decl., Ex. 1.

¹² ECF No. 315.

¹³ Complaint at ¶177.

that agreement. That occurred before the alleged anticompetitive reverse payment settlement agreement between Merck and Glenmark was executed. That distribution agreement was first produced by Merck and Glenmark in November 2018.

Thereafter, plaintiffs' counsel immediately sought discovery from both Merck and Glenmark specifically directed to the breadth and extent of Par's involvement. Subsequent productions from Merck and Glenmark over the next several months, amounting to over two million pages of documents, confirmed plaintiffs' view that Par should be added as a defendant.

Settlement negotiations between Direct Purchaser Class Plaintiffs and Par have been at arm's length, and occurred over the course of months. The Settlement provides that Par will produce agreed-upon discovery, including documents, data and deposition testimony, on an expedited basis, will provide a witnesses or witnesses at trial of the claims against Merck and Glenmark, and covenants not to bring or assert antitrust claims or counterclaims against Merck or Glenmark relating to the conduct alleged in this lawsuit.¹⁴ In exchange, the Direct Purchaser Settlement Class will dismiss (and release) their claims against Par with prejudice and seek a stay of all proceedings against Par in the MDL.¹⁵

C. The proposed Direct Purchaser Settlement Class.

For purposes of the Settlement only, the Direct Purchaser Class Plaintiffs seek certification (for Settlement purposes only) of a class of:

All persons or entities in the United States and its territories that purchased Zetia or generic Zetia in any form directly from Merck, Glenmark/Par, or any agents, predecessors, or successors thereof from December 6, 2011 until June 11, 2017 (the "Direct Purchaser")

¹⁴ Sobol Decl. Ex. 1 at ¶ 1 and Exhibit A thereto.

¹⁵ Sobol Decl. Ex. 1 at ¶¶ 12, 16(b), 17.

Settlement Class").16

Excluded from the Direct Purchaser Settlement Class are defendants Merck, Glenmark and Par, and their officers, directors, management, employees, parents, subsidiaries, or affiliates, and the government of the United States and all agencies thereof, and all state or local governments and all agencies thereof.

III. ARGUMENT

A. The Direct Purchaser Settlement Class should be certified for settlement purposes pursuant to Rule 23.

Courts often routinely certify classes of direct purchasers alleging that a name-brand drug maker wrongfully impeded market entry of generic drugs, both for litigation and settlement.¹⁷

This district recently certified both a litigation class and a settlement class in a generic delay

¹⁶ This definition of the Direct Purchaser Settlement Class differs from the definition set forth in Direct Purchaser's Amended Consolidated Class Action Complaint (ECF No. 250-1). Unlike the class definition in the Amended Complaint, the current definition does not include entities who purchased from manufacturers other than Merck, Glenmark and Par.

¹⁷ See, e.g., Am. Sales Co., LLC v. Pfizer, Inc., No. 2:14-cv-361, 2017 WL 3669604, at *17 (E.D. Va. July 28, 2017), report and recommendation adopted, No. 2:14-cv-361, 2017 WL 3669097 (E.D. Va. Aug. 24, 2017) ("In re Celebrex"); In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., No.14-md-02503, 2017 WL 4621777, at *22 (D. Mass. Oct. 16, 2017); In re Lidoderm Antitrust Litig., No. 14-md-2521, 2017 WL 679367 (N.D. Cal. Feb. 21, 2017); In re Nexium (Esomeprazole) Antitrust Litig., 296 F.R.D. 47 (D. Mass. 2013) ("Nexium"); In re Neurontin Antitrust Litig., MDL No., 1479, 2011 WL 286118 (D.N.J. Jan. 25, 2011); Am. Sales Co. v. SmithKline Beecham Corp., 284 F.R.D. 127 (E.D. Pa. 2010) ("Flonase"); In re Wellbutrin SR Direct Purchaser Antitrust Litig., No. 04-cv-5525, 2008 WL 1946848 (E.D. Pa. May 2, 2008) ("Wellbutrin SR"); Teva Pharms. USA, Inc. v. Abbott Labs., 252 F.R.D. 213 (D. Del. 2008) ("TriCor"); In re Relafen Antitrust Litig., 218 F.R.D. 337 (D. Mass. 2003) ("Relafan"); In re DDAVP Direct Purchaser Antitrust Litig., 05-cv-2237, 2011 WL 12627961 (S.D.N.Y. Aug. 15, 2011); In re Metoprolol Succinate Direct Purchaser Antitrust Litig., No. 06cv-052, 2011 WL 13097266 (D. Del. Nov. 16, 2011). Courts have also certified classes of direct purchasers in analogous antitrust cases alleging that brand companies suppressed competition from less expensive rivals. See, e.g., Meijer, Inc. v. Abbott Labs., No. 07-cv-985, 2008 WL 4065839 (N.D. Cal. Aug. 27, 2008) (certifying class challenging market exclusion of lessexpensive drugs) ("Norvir"); Nexium, 296 F.R.D. at 60; In re Prograf Antitrust Litig., 2013 WL 2395083 (D. Mass. April 23, 2013) ("Prograf") (certifying class of direct purchasers alleging brand company engaged in anticompetitive behavior to unlawfully delay generic competition).

case, where direct purchasers alleged that the brand manufacturer of the drug Celebrex fraudulently obtained a patent for its drug Celebrex.¹⁸

The Fourth Circuit recognizes that "federal courts should 'give Rule 23(a) a liberal rather than a restrictive construction, adopting a standard of flexibility in application which will in the particular case best serve the ends of justice for the affected parties and . . . promote juridical efficiency." Court decisions certifying classes of direct purchasers of pharmaceutical products challenging suppression of generic competition supply a compelling blueprint for certification here. Those decisions involve essentially the same proposed class, some of the same proposed class representatives and counsel, and analogous fact patterns, legal claims, and relief sought. As detailed below, the proposed Direct Purchaser Settlement Class satisfies the requirements of Rules 23(a) and (b). Accordingly, certification is appropriate.

1. The Direct Purchaser Settlement Class satisfies all Rule 23(a) requirements.

Rule 23(a) requires: (1) the class is so numerous as to make joinder of all members impracticable; (2) there exist questions of fact or law common to the class; (3) the representative parties' claims or defense are typical of those of the class; and (4) the representative parties – plaintiffs and counsel – will fairly and adequately protect the class's interests. Direct Purchaser Class Plaintiffs satisfy these requirements.

¹⁸ See, e.g., In re Celebrex, 2017 WL 3669604 at *17-18; In re Celebrex, 2:14-cv-361 (ECF No. 615

¹⁹ *Gunnells v. Healthplan Servs., Inc.*, 348 F.3d 417, 424 (4th Cir. 2003) (quoting *In re A.H. Robins Co., Inc.*, 880 F.2d 709, 740 (4th Cir. 1989)).

²⁰ Settlement classes must meet Rule 23's requirements for certification other than as to manageability. *See Amchem Prod., Inc. v. Windsor*, 521 U.S. 591, 619-620 (1997).

a. The widely dispersed Direct Purchaser Settlement Class members makes joinder impractical.

Regarding numerosity, the Fourth Circuit instructs that "[n]o specified number is needed to maintain a class action" and has upheld the certification of classes as few as 18 class members even when those class members were all located in the same area. Joinder is generally impracticable where the Class includes 40 or more members, and courts have certified far smaller classes in similar cases, including in this Court. The proposed Class here includes seventy-one (71) members, easily meeting these thresholds.

Joinder is also impracticable here because the proposed class is geographically dispersed throughout the country.²⁶ As one court in this District has made clear, where, as here, "class members are not centrally located" and reside in multiple states, as here, "[t]his factor weighs in

²¹ Brady v. Thurston Motor Lines, 726 F.2d 136, 145 (4th Cir. 1984) (quoting Cypress v. Newport News Gen. & Nonsectarian Hosp. Ass'n., 375 F.2d 648, 653 (4th Cir. 1967)).

²² Cypress, 375 F.2d at 653.

²³ E.g., Peoples v. Wendover Funding, Inc., 179 F.R.D. 492, 497 (D. Md. 1998) ("[G]enerally, courts find classes of at least 40 members sufficiently large to satisfy the impracticability requirement.").

²⁴In re Celebrex, 2017 WL 3669604, at *17 (finding a class of 32 direct drug purchasers sufficiently numerous); Nexium, 296 F.R.D. at 51 (24-29 members); Prograf, 2013 WL 2395083, at *1 (25 members); Wellbutrin XL, 2011 WL 3563385, at *3-4 (33 members); Flonase, 274 F.R.D. at 133 (33 members); Meijer, Inc. v. Warner Chilcott Holdings Co. III, Ltd., 246 F.R.D. 293, 305-06 & n.14 (D.D.C. 2007) ("Ovcon") (30 members); see also Fangman v. Genuine Title, LLC, No. 14-cv-81, 2016 WL 6600509, at *8 (D. Md. Nov. 8, 2016) (A "class consisting of as few as 25 to 30 members raises the presumption that joinder would be impractical.") (citation and quotations omitted)).

²⁵ Sobol Decl. Ex. 5, (Declaration of Lynette Hilton, Ph.D., July 15, 2019), at ¶ 38, n72.

²⁶ *Id.*, Ex. 5 (list of 71 class members); *see Celebrex*, 2017 WL 3669604, at *10 ("the class of thirty-two direct purchasers is comprised of companies . . . spread across the United States and Puerto Rico. Such geographic dispersion regularly weighs in favor of an impracticability finding"). *Solodyn*, 2017 WL 4621777, at *5 (widespread "geographic dispersion" "suggests joinder is impracticable, even when putative class members are corporate entities.")

favor of finding numerosity because the nationwide dispersion makes joinder of all plaintiffs an unwieldy prospect."²⁷

In addition, joinder here is impracticable because "direct purchasers sometimes may refrain from bringing a treble-damages suit for fear of disrupting relations with their suppliers." Retaliation against plaintiffs has occurred in pharmaceutical antitrust class cases. ²⁹

Finally, to the extent that members of the class must be "clearly ascertainable," they are here. The requirements of Rule 23(a)(1) are therefore satisfied.

b. The present case involves issues of law and fact that are common to the Direct Purchaser Settlement Class.

Rule 23(a)(2) requires questions of law or fact common to the class.³² "A common question is one that can be resolved for each class member in a single hearing" and does not "turn on a consideration of the individual circumstances of each class member."³³ Rule 23(a)(2) does not require that *every* question of fact and law be common to the class. Rather, a class's claims must involve "a common contention . . . of such a nature that it is capable of classwide resolution" and it should have the capacity to "generate common *answers* apt to drive the

²⁷ *Milbourne v. JRK Residential Am., LLC*, No. 12-cv-861, 2014 WL 5529731, at *5 (E.D. Va. Oct. 31, 2014) (noting that "the size of the proposed class, numbering 43, also weighs in favor of finding numerosity").

²⁸ *Ill. Brick*, 431 U.S. at 746.

²⁹ See, e.g., Rochester Drug Coop., Inc. v. Braintree Labs., 796 F. Supp. 2d 560, 567 (D. Del. 2011) ("[T]here is no dispute that defendant at bar terminated its business relationship with plaintiffs specifically as a result of plaintiffs' pursuit of [pharmaceutical antitrust] litigation").

³⁰ *In re Delta/AirTran Baggage Fee Antitrust Litig.*, 317 F.R.D. 675, 679 (N.D. Ga. 2016) (quoting *Little v. T-Mobile USA, Inc.*, 691 F.3d 1302, 1304 (11th Cir. 2012)).

³¹ See Sobol Decl., Ex. 5 (Hilton Decl.), Ex. 5 (listing 71 Direct Purchaser Settlement Class members).

³² Wal-Mart Stores, Inc. v. Dukes, 564 U.S. 338, 350 (2011).

³³ Thorn v. Jefferson-Pilot Life Ins. Co., 445 F.3d 311, 319 (4th Cir.2006).

resolution of the litigation."³⁴ Demonstrating commonality does not require proof that the putative class will prevail on whatever common questions it identifies. "Certification is only concerned with the commonality (not the apparent merit) of the claims"³⁵

Courts in this district observe "[g]enerally, antitrust plaintiffs are found to have satisfied this element in their complaint as an allegation of conspiracy or monopolization will generally be treated as a 'central' or 'single overriding' issue or, 'common nucleus of operative fact' sufficient to establish a common question."³⁶ In this case, as in all antitrust cases alleging delayed generic entry, all class members allege injury due to the same misconduct.³⁷

c. Direct Purchaser Settlement Class' claims are typical.

Rule 23(a)(2) also requires typicality. "A plaintiff's claim is typical if it arises from the same event, practice, or course of conduct that gives rise to the claims of other class members, and if the plaintiff's claim is based on the same legal theory as those of the other members." The typicality requirement does not require named plaintiffs' claims be "identical to" or "co-

³⁴ Wal-Mart, 564 U.S. at 350 (quoting Richard A. Nagareda, Class Certification in the Age of Aggregate Proof, 84 N.Y.U. L. Rev. 97, 132 (2009)).

³⁵ Brown v. Nucor Corp., 576 F.3d. 149, 152 (4th Cir. 2009) (quoting Lilly v. Harris-Teeter Supermarket, 720 F.2d 326, 332-33 (4th Cir. 1983)).

³⁶ Brown v. Cameron-Brown Co., 92 F.R.D. 32, 38 (E.D. Va. 1984); see Ballard v. Blue Shield of S. W. Va., Inc., 543 F.2d 1075, 1080 (4th Cir. 1976) ("Class actions are frequently maintained in antitrust cases because of the many questions of law and fact that are common to the members of the class.")

³⁷ See, e.g., Wellbutrin XL, 2011 WL 3563385, at *4 (direct purchaser class members' claims depended on common issues, e.g., whether "defendants engaged in a scheme to delay the entry of less expensive generic versions" resulting in delayed generic entry); Wellbutrin SR, 2008 WL 1946848, at *2 (similar); TriCor, 252 F.R.D. at 225 (similar); K-Dur, 2008 WL 2699390, at *4-5 (similar); Nifedipine, 246 F.R.D. at 368-69 (similar); Ovcon, 246 F.R.D. at 300 (similar); Premarin, 225 F.R.D. at 213 (similar); Relafen, 218 F.R.D. at 342 (similar); In re Buspirone Patent & Antitrust Litig., 210 F.R.D. 43, 57 (S.D.N.Y. 2002) ("Buspirone"); In re Cardizem CD Antitrust Litig., 200 F.R.D. 297, 303-04(E.D. Mich. 2001) (similar).

³⁸ Velasquez-Monterrosa v. Mi Casita Restaurants, No. 5:14-cv-448, 2016 WL 1703351, at *5 (E.D.N.C. Apr. 27, 2016) (citation omitted).

extensive with" those of the class.³⁹ The typicality requirement "has been liberally construed by courts . . . [and] in the antitrust context, typicality will be established by plaintiffs and all class members alleging the same antitrust violations by defendants."⁴⁰

All courts in similar delayed generic competition cases have found the typicality prong met because, as here, plaintiffs asserted that defendants' conduct had delayed generic competition, and sought overcharges for themselves and the class.⁴¹

d. There are no conflicts and Direct Purchaser Class counsel are experienced in complex antitrust class litigation.

Rule 23(a)(4) requires adequacy of representation. "This inquiry 'serves to uncover conflicts of interest between named parties and the class they seek to represent." "42

To meet its burden, "the moving party must show first that the interests of the representative party will not conflict with the interests of any of the class members, and second, that counsel chosen by the representative party is qualified, experienced and able to vigorously conduct the proposed litigation."⁴³ Direct Purchaser Class Plaintiffs meet both of these criteria and satisfy the adequacy of representation requirement.

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³⁹ *Nat'l Constructors Ass'n v. Nat'l Elec. Contractors Ass'n*, 498 F. Supp. 510, 545 (D. Md. 1980) (quoting *In re Four Seasons Sec. Laws Litig.*, 59 F.R.D. 667, 681 (W.D. Okl. 1973), *rev'd on other grounds*, 502 F.2d 834 (10th Cir. 1974)).

⁴⁰ *In re Titanium Dioxide Antitrust Litig.*, 284 F.R.D. 328, 339 (D. Md. 2012) (internal quotations and citations omitted).

⁴¹ E.g., Wellbutrin XL, 2011 WL 3563385, at *4; TriCor, 252 F.R.D. at 226; Wellbutrin SR, 2008 WL 1946848, at *3; K-Dur, 2008 WL 2699390, at *6; Nifedipine, 246 F.R.D. at 368-69; Ovcon, 246 F.R.D. at 301-02; Relafen, 218 F.R.D. at 343; Buspirone, 210 F.R.D. at 57; Cardizem, 200 F.R.D. at 304-05.

⁴² In re Celebrex, 2017 WL 3669604, at *12 (quoting Amchem Prod., Inc., v. Windsor, 521 U.S. 591, 625 (1997)).

⁴³ Relafen, 218 F.R.D. at 343 (quoting Andrews v. Bechtel Power Corp., 780 F.2d 124, 130 (1st Cir. 1985)).

(1) Absence of conflict.

Under Rule 23(a)(4), any potential conflict "'must be more than merely speculative or hypothetical," but rather go "to the heart of the litigation." Where a defendant's actions form the basis of the antitrust claim, "named plaintiffs and their counsel have the same core objectives as would absent class members." In this case, as in similar prior cases, "because *Hanover Shoe* sets the amount of the overcharge as direct purchasers' damages, all of the class members have the same financial incentive for purposes of the litigation – *i.e.*, proving that they were overcharged and recovering damages based on that overcharge."

Direct Purchaser Class Plaintiffs satisfy the adequacy of representation requirement of Rule 23(a)(4) because "all class members have the right to pursue overcharge damages, they have the same incentive to do so, and there is no conflict among class members allegedly harmed by the same antitrust violation."

(2) Qualifications of counsel

The Court previously entered an order appointing Hagens Berman Sobol Shapiro LLP (HBSS) as Interim Co-Lead Class Counsel for Direct Purchaser Plaintiffs pursuant to Rule 23(g),

⁴⁴ *Gunnells*, 348 F.3d at 430 (quoting 5 Moore's Federal Practice § 23.25[4][b][ii] (2002); *see also Ward v. Dixie Nat. Life Ins. Co.*, 595 F.3d 164, 180 (4th Cir. 2010) ("A conflict is not fundamental when, as here, all class members 'share common objectives and the same factual and legal positions [and] have the same interest in establishing the liability of [defendants].") (quoting *Gunnells*, 348 F.3d at 431); *Soutter v. Equifax Info. Servs., LLC*, 307 F.R.D. 183, 213 (E.D. Va. 2015).

⁴⁵ *In re Carbon Black Litig.*, MDL No. 1453, 2005 WL 102966, at *14 (D. Mass. Jan. 18, 2005) (citation omitted).

⁴⁶ *K-Dur*, 686 F.3d at 223 (citing 7A Charles Alan Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure § 1768 (3d ed. 2005); *see also Warfarin*, 391 F.3d at 532.

⁴⁷ Wellbutrin SR, 2008 WL 1946848 at *6; see also Relafen, 218 F.R.D. at 343 ("Louisiana Wholesale asserts claims typical of those of the class, claiming similar injuries, suffered during the same period and arising from the same conduct.").

(d)(1)(C), and (d)(1)(E).⁴⁸ Since then, HBSS – which has extensive experience prosecuting pharmaceutical antitrust cases like this⁴⁹ – has worked harmoniously and efficiently with other counsel for the Direct Purchaser Class Plaintiffs. Together, these firms have extensive experience in antitrust class actions, showing time and again that they treat their fiduciary duties toward absent class members with the utmost seriousness.⁵⁰ One or more of these firms, and/or the individual lawyers prosecuting this case, has served as lead or co-lead counsel for purchaser classes in virtually all of the pharmaceutical antitrust actions cited in this submission, including, but not limited to, *Celebrex, Solodyn, Lidoderm, Nexium, Neurontin, Flonase, K-Dur, Wellbutrin SR, Wellbutrin XL, Relafen*, and others.

Direct Purchaser Class Plaintiffs request, under Rule 23(g), to have HBSS serve in the same capacity once the Direct Purchaser Settlement Class has been certified. This Court has already witnessed first-hand. HBSS is well-qualified and satisfies the standards of Rules 23(a)(4) and 23(g).

2. The Direct Purchaser Settlement Class satisfies all Rule 23(b)(3) requirements.

Rule 23(b)(3) requires that: (1) common questions of law or fact predominate over individual questions and (2) a class action is superior to other available methods of adjudication. The Direct Purchaser Settlement Class satisfies both requirements here.

⁴⁸ See ECF No. 105.

⁴⁹ See, e.g., Wellbutrin XL, 2011 WL 3563385 at *5 (finding class counsel Hagens Berman Sobol Shapiro LLP "well-qualified": "The plaintiff's counsel are well-qualified to represent the proposed class in this case. They have extensive experience in similar class actions involving delayed generic competition. The plaintiff's counsel also have vigorously and capably prosecuted this action.") (citations omitted); *Prograf*, 2013 WL 2395083 at *2 (finding class counsel, Hagens Berman Sobol Shapiro LLP, "well-qualified");

⁵⁰ See Sobol Decl. Ex. 7 (HBSS Boston Office Resume).

a. Common questions of law or fact predominate over individual questions

Predominance is "a test readily met in certain cases alleging . . . violations of the antitrust laws." Predominance requires that "*questions* common to the class predominate, not that those questions will be answered, on the merits, in favor of the class." [T]he office of a Rule 23(b)(3) certification ruling is not to adjudicate the case; rather, it is to select the 'metho[d]' best suited to adjudication of the controversy 'fairly and efficiently."

The Supreme Court has explained that "Rule 23(b)(3) . . . does *not* require a plaintiff seeking class certification to prove that each 'elemen[t] of [her] claim [is] susceptible to classwide proof" but rather that "common questions 'predominate over any questions affecting only individual [class] members." [C]ommon liability issues such as conspiracy or monopolization have, almost invariably, been held to predominate over individual issues." At class certification, "[p]laintiffs need only show by a preponderance of the evidence that these elements are 'capable of proof at trial through evidence that is common to the class rather than individual to its members." 56

⁵¹ Cordes & Co. Fin. Servs., Inc. v. A.G. Edwards & Sons, Inc., 502 F.3d 91, 108 (2d Cir. 2007) (quoting Amchem, 521 U.S. at 625).

⁵² Amgen Inc. v. Connecticut Ret. Plans & Tr. Funds, 568 U.S. 455, 460 (2013); see also id. (plaintiffs' claims "will prevail or fail in unison," as required by Rule 23(b)(3)).

³³ Id

⁵⁴ *Id.* at 469 (quoting Fed. R. Civ. P. 23(b)(3) (emphasis in original)).

⁵⁵ 6 Hubert Newberg & Alba Conte, *Newberg on Class Actions* § 18.25 (3d ed. 1992); *see also id.* at § 18.29 ("[T]he monopolization issue is likely to predominate within the meaning of Rule 23(b)(3)."); 7B Alan Wright, Arthur R. Miller & Mary Kay Kane, *Federal Practice & Procedure* § 1781 (2004) ("[W]hether a conspiracy exists is a common question that is thought to predominate over the other issues in the case").

⁵⁶ Titanium Dioxide, 284 F.R.D. at 344 (quoting *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305 (3d Cir.. 2008)) (emphasis added); *In re Static Random Access Memory (SRAM) Antitrust Litig.*, 264 F.R.D. 603, 612 (N.D. Cal. 2009) ("On a motion for class certification, the Court only evaluates whether the method by which plaintiffs propose to prove class-wide impact could prove such impact, not whether plaintiffs in fact can prove class-wide impact." (quoting *In*

The Court has a "duty to take a 'close look' at whether common questions predominate over individual ones."⁵⁷ That "close look" shows that, as in every prior case alleging suppressed generic drug competition,⁵⁸ the predominance standard is met here as to every element of the direct purchasers' claims: (1) violation of the antitrust laws; (2) impact; and (3) damages.

(1) Proof of antitrust violations uses predominantly common evidence.

Direct Purchaser Class Plaintiffs allege that Glenmark/Par conspired and entered into agreements with Merck to unreasonably restrain trade in violation of Section 1 of the Sherman Act.⁵⁹ The Section 1 claims at issue are governed by the "rule of reason," and require proof of: "(1) the existence of a contract, combination or conspiracy among two or more separate entities that (2) unreasonably restrains trade and (3) affects interstate and foreign commerce." ⁶¹

Proof of the unlawful conspiracy "relates solely to Defendants' conduct" and does "not vary among class members." Direct Purchaser Class Plaintiffs allege that Merck and Glenmark/Par entered into unlawful pay-for-delay agreements that had the intent and effect of

re Magnetic Audiotape Antitrust Litig., No. 99 Civ 1580, 2001 WL 619305, at *4 (S.D.N.Y. June 6, 2001))); see also K-Dur, 686 F.3d at 222 ("[F]or certification plaintiff need not prove antitrust injury actually occurred."); DRAM, 2006 WL 1530166, at *9 ("Plaintiffs need only advance a plausible methodology to demonstrate that antitrust injury can be proven on a class-wide basis.").

⁵⁷ Comcast Corp. v. Behrend, 569 U.S. 27, 34 (2013) (quoting Amchem, 521 U.S. at 615).

⁵⁸ See supra note 41.

⁵⁹ Complaint ¶¶4, 324-333.

⁶⁰ FTC v. Actavis, Inc., 133 S. Ct. 2223, 2227 (2013).

⁶¹ *Thompson Everett, Inc. v. Nat'l Cable Advert., L.P.*, 850 F. Supp. 470, 479 (E.D. Va. 1994), *aff'd*, 57 F.3d 1317 (4th Cir. 1995) (citation omitted).

⁶² In re Lorazepam & Clorazepate Antitrust Litig., 202 F.R.D. 12, 29 (D.D.C. 2001) (citation omitted); see also In re Celebrex, 2017 WL 3669604, at *13 ("Courts deciding whether to certify a class in delayed-entry cases like this one frequently find that common questions of fact and law will predominate when there has been an alleged violation of antitrust law..... And in fact, as is true in this case, predominance of common issues in determining antitrust violations is rarely contested.") (citations omitted).

delaying entry of generic Zetia into the market. They further allege that this conduct wrongfully maintained Merck's monopoly power in the market for ezetemibe by (a) impairing generic Zetia competition, and thereby (b) forcing direct purchasers to buy more-expensive branded Zetia rather than substituting less-expensive (but essentially identical) AB-rated generic versions of Zetia, paying more for generic Zetia, and/or obtaining lower prices for branded Zetia once it faced unimpaired generic competition.⁶³

If class members pursued this case individually, each would have to prove the same course of conduct, using the same documents and witnesses. Predominance is therefore satisfied on the issue of antitrust violation.⁶⁴

(2) Proof of antitrust impact uses predominantly common evidence.

Antitrust injury, or impact, requires a showing of "some damage" due to a defendant's antitrust violations.⁶⁵ "[O]n a motion for class certification, the Court only evaluates whether

⁶³ Complaint ¶¶4, 324-333.

⁶⁴ See TriCor., 252 F.R.D. at 228 ("[T]he court finds that each putative class member, had they pursued their claims individually, would have been required to prove identical facts, such as defendants' monopoly power, exclusionary scheme, effect on interstate commerce, conspiracy, and unreasonable restraint of trade. Therefore, these common issues predominate over any individual issues relating to proof of an antitrust violation"); see also Flonase, 274 F.R.D. at 135 ("Direct Purchasers' Section 2 claim requires proof of GSK's actions and intent. Such proof will necessarily be class-wide – GSK's actions did not vary with respect to individual direct purchasers, aside from the price charged. . . . "); In re K-Dur Antitrust Litig., No. 01-cv-1652, 2008 WL 2660723, at *8 (D.N.J. Mar. 27, 2008) ("[c]ourts routinely find that proof of a violation of the antitrust law focuses on the defendants' conduct and not on the conduct of individual class members"); In re Nifedipine Antitrust Litig., 246 F.R.D. 365, 369 n.5 (D.D.C.2007) ("[w]hether [defendants' actions] constituted a 'conspiracy' . . . is an issue common to all prospective plaintiffs") (predominance standard satisfied); Ovcon, 246 F.R.D. at 308 ("the Court notes that because the alleged violation here relates solely to Defendants' conduct[,] proof for this issue will not vary among class members") (citations, quotation, and alterations omitted) (predominance standard satisfied).

⁶⁵ Zenith Radio Corp. v. Hazeltine Research, 395 U.S. 100, 114, n.9 (1969).

the method by which plaintiffs propose to prove classwide impact could prove such impact, not whether plaintiffs in fact can prove class-wide impact."⁶⁶

Direct Purchaser Class Plaintiffs allege injury here (as in all prior generic suppression cases) in the form of overcharges.⁶⁷ Direct Purchaser Class Plaintiffs allege that, absent Defendants' wrongful conduct, unimpaired generic Zetia competition would have occurred beginning in December 2011 and as a result of this unimpaired generic Zetia competition, the class would have paid less for its purchases of ezetimibe (a) by substituting less-expensive generic ezetimibe for more-expensive branded Zetia, and/or paying less for generic Zetia; and/or (b) by receiving greater discounts on their remaining purchases of branded Zetia (*i.e.*, by paying less for branded Zetia). Direct Purchaser Class Plaintiffs allege that all or nearly all class members were injured because absent Defendants' conduct all or nearly all class members would have paid less for their purchases of ezetimibe.

Dr. Lynette Hilton, an economist experienced in delayed generic entry cases, has concluded that (1) Defendants' allegedly unlawful conduct, if proven, had a direct, market-wide effect on ezetimibe prices generally (*i.e.*, maintaining the prices above the level that would have obtained absent Defendants' allegedly unlawful conduct), and (2) all or nearly all members of the Direct Purchaser Settlement Class would have paid less for their purchases of ezetimibe absent Defendants' allegedly unlawful conduct.⁶⁸

⁶⁶ SRAM, 264 F.R.D. at 612 (citation omitted); see also K-Dur, 686 F.3d at 222 ("for certification plaintiff need not prove antitrust injury actually occurred"); Relafen, 218 F.R.D. at 344-346; Nexium, 296 F.R.D. at 31; Prograf, 2013 WL 2395083 at *3.

⁶⁷ See Hanover Shoe, Inc. v. United Machinery Corp., 392 U.S. 481, 489 (1968) ("[W]hen a buyer shows that the price paid by him for materials purchased for use in his business is illegally high and also shows the amount of the overcharge, he has made out a prima facie case of injury and damage within the meaning of § 4").

⁶⁸ Sobol Decl., Ex. 5 (Hilton Decl.) at ¶¶ 7, 36-40.

In her declaration, Dr. Hilton sets forth several types of evidence, all of which is common to the class, that both independently and in combination support her conclusion that all or nearly all members of the proposed class incurred at least some overcharges from impaired generic Zetia entry and competition, and therefore suffered antitrust injury.⁶⁹

First, Dr. Hilton reviews the extensive body of empirical economic research demonstrating that generic products are both substantially less expensive than brands and rapidly substituted for their brand counterparts. This research demonstrates that unconstrained generic competition reduces prices paid primarily because AB-rated generics are priced substantially lower than their branded counterparts and quickly capture unit sales formerly enjoyed by the brand, because brand manufacturers launched their own "authorized generics" to compete on price and may offer brand discounts to retain purchasers following generic entry, and because the generic prices are lower with more generic competitors on the market. This research, all common and class-wide in nature, further shows the competitive effects of unimpaired generic entry and is strong evidence of the class-wide antitrust impact of Defendants' alleged conduct at issue here.

Second, Dr. Hilton points to contemporaneous forecasting documents, prepared for business purposes by each of the Defendants, and by other generic manufacturers, which support the Direct Purchaser Class Plaintiffs' allegations that, with unimpaired generic competition, generic Zetia would be priced lower than branded Zetia, and would quickly capture most of the

⁶⁹ *Id*. at ¶ 21.

⁷⁰ *Id.* at ¶¶ 22-28 (citing for example: (1) a 2009 FTC Study that found generics captured between 72 and 85 percent of sales in the first six months; and (2) a 2010 FTC Study that concluded that generic penetration rate is 90 percent on average approximately one year after generic entry).

⁷¹ *Id*.

branded Zetia sales.⁷² These forecasts are market-wide evidence, common to all class members, that support Direct Purchaser Class Plaintiffs' allegations that delaying generic entry impacts all or nearly all members of the class by preventing them from obtaining the substantial savings unimpaired generic competition would have caused.⁷³

Third, Dr. Hilton also considers what actually happened following the launch of generic Zetia, and following generic entry as allowed under the challenged agreements, starting in December, 2016.⁷⁴ IMS data shows that the Class paid less for generic Zetia than for branded Zetia during Par's first six months on the market, and paid even less for generic Zetia following generic entry by other generic manufacturers. The data also indicates that once generic entry occurred, the cost of branded Zetia also declined.⁷⁵

Finally, Dr. Hilton points out that the Class members are all wholesalers or retailers who supplied branded or generic Zetia to broad cross-sections of customers, and concludes that, because class members supply broad cross-sections of customers, all or nearly all class members would have paid less for ezetimibe had generic competition not been impaired by Defendants' unlawful actions, including by substituting less-expensive generic Zetia purchases for the class's purchases of more expensive brand Zetia and paying less for their purchases of generic Zetia.⁷⁶

These are precisely the kinds of common evidence that other courts in cases involving delayed generic drug entry have found sufficient to satisfy the plaintiffs' burden to show class maintainability on the issue of antitrust impact.⁷⁷ Because antitrust impact may be proven

 $^{^{72}}$ Sobol Decl., Ex. 5 (Hilton Decl.) at $\P\P$ 29-33.

 $^{^{73}}$ *Id.* at ¶ 33.

⁷⁴ *Id.* at ¶¶ 34-35, figure 2.

⁷⁵ I.A

⁷⁶ *Id.* at ¶ 38-40.

 $^{^{77}}$ See, e.g., In re Celebrex, 2017 WL 3669604, at *15-16; Nexium, 296 F.R.D. at 55-58;

through evidence that is predominantly or entirely common to the class, and because the evidence shows that all or nearly all class members suffered antitrust impact from Defendants' alleged conduct, the Direct Purchaser Settlement Class meets the predominance standard here.

(3) Direct Purchaser Class Plaintiffs can calculate damages on an aggregate basis at the appropriate time.

Direct Purchaser Class Plaintiffs advance only one theory of antitrust impact: suppression of generic Zetia competition through alleged pay-for-delay agreements between Merck and Glenmark/Par. Direct Purchaser Class Plaintiffs' expert can measure overcharges resulting from Defendants' allegedly unlawful conduct on an aggregate, classwide basis. Dr. Hilton's team at Econ One has developed similar damage calculations in a number of prior, similar cases, all using common evidence. Overcharge damages arise from the difference between the actual prices that Class members paid for ezetimibe and the prices the Class would have paid for ezetimibe had generic competition not been impaired.

Dr. Hilton explains that calculating aggregate Class damages on a formulaic basis, will utilize and rely only on evidence that is common to the Class.⁸⁰ The ability to calculate

Lidoderm, 2017 WL 679367, at *9; *K-Dur*, 686 F.3d at 220 (expert's analysis that purchasers paid more due to delayed generic entry "satisfactorily explained [plaintiffs'] theory of impact") (citation omitted); *Wellbutrin SR*, 2008 WL 1946848, at *8, *42-43 (plaintiff's expert relied upon "literature examining the impact of generic entry into the pharmaceutical market and analysis of public data collected on dispensation and purchases of prescription drugs"); *TriCor*, 252 F.R.D. at 229-30 ("scholarly economic literature, governmental studies and empirical evidence analyzing the market wide effects of unfettered generic competition on the prices and market shares of both brand and generic drugs"); *Ovcon*, 246 F.R.D. at 308-10 (economic literature, generic projections and sales data); *Nifedipine*, 246 F.R.D. at 370 & n.10 (same); *Premarin*, 225 F.R.D. at 218 (same); *Relafen*, 218 F.R.D. at 343-46 (same); *Buspirone*, 210 F.R.D. at 58 (same); *Cardizem*, 200 F.R.D. at 307-21 (same).

⁷⁸ Sobol Decl., Ex. 5 (Hilton Decl.), at ¶¶ 41-48.

⁷⁹ *Id.* at ¶ 44.

⁸⁰ *Id.* at ¶48. Class certification is proper even if the class includes some uninjured members. *See, e.g.*; *K-Dur*, 686 F.3d at 221-22 (certification appropriate even if some class members might have "zero" or "negative" damages where "all (or virtually all) members of the proposed class"

aggregate Class damages using common evidence supports certification and a finding of predominance.⁸¹

b. Class action treatment of the case is superior to other methods.

The "superiority" requirement of Rule 23(b)(3) ensures that resolution by class action will "achieve economies of time, effort, and expense, and promote ... uniformity of decision as to persons similarly situated, without sacrificing procedural fairness or bringing about other undesirable results."82

Certifying this settlement class is superior to any other method that may exist for resolving this case or controversy, as required by Rule 23(b)(3). Considerations of judicial efficiency favor concentrating this litigation in one forum. Allowing the Direct Purchaser Settlement Class to move forward in a settlement class action would (1) avoid congesting the

were harmed); *In re Cathode Ray Tube (CRT) Antitrust Litig.*, 308 F.R.D. 606, 616 (N.D. Ca. July 8, 2015) ("The mere 'possibility or indeed inevitability' of including a member in the class who ultimately, at the end of trial, turns out to lack standing does not prevent class certification.") (quotation and citation omitted); *In re Rubber Chems. Antitrust Litig.*, 232 F.R.D. 346, 353 (N.D. Ca. Oct. 6, 2005) ("[F]or purposes of class certification, it is not necessary for Plaintiffs to show that every single class member was injured by the alleged price-fixing conspiracy."); *Norvir*, 2008 WL 4065839, at *8 ("To proceed as a class action, Plaintiffs must be able to establish, predominantly with generalized evidence, that all (or nearly all) members of the class suffered damage as a result of Abbott's alleged anti-competitive conduct.") (emphasis added); *Kohen v. Pac. Inv. Mgmt. Co. LLC*, 571 F.3d 672, 677 (7th Cir. 2009) ("a class will often include persons who have not been injured by the defendant's conduct. . . . "Such a possibility or indeed inevitability does not preclude class certification") (citations omitted); *DG v. Devaughn*, 594 F.3d 1188, 1198 (10th Cir. 2010) ("a class will often include persons who have not been injured by the defendant's conduct") (citation omitted).

⁸¹ See generally, Lidoderm, 2017 WL 679367, at *9-13.

⁸² Amchem Prods. v. Windsor, 521 U.S. 591, 615 (1997); see also Gunnells, 348 F.3d at 432 ("[T]he size of class members' recovery is hardly determinative of superiority."); Smilow v. Southwestern Bell Mobile Sys., Inc. 323 F.3d 32, 41-42 (1st Cir. March 7, 2003) ("The policy at the very core of the class action mechanism is to overcome the problem that small recoveries do not provide the incentive for any individual to bring a solo action prosecuting his or her rights. A class action solves this problem by aggregating the relatively paltry potential recoveries into something worth someone's (usually an attorney's) labor.") (internal citations omitted).

courts with the need to repetitively adjudicate such actions; (2) prevent the possibility of inconsistent results; and (3) allow smaller class members an opportunity for redress they might otherwise be denied. This is consistent with the approach taken by all other courts in direct purchaser generic suppression cases.⁸³

B. The proposed Settlement meets the standard for preliminary approval.

Preliminary approval of a proposed class action settlement under Fed. R. Civ. P. 23(e) is the first step in a two-step process.⁸⁴ At the preliminary approval stage, courts make an initial evaluation of the fairness of the settlement terms.⁸⁵ Rule 23(e) instructs that a class action "may be settled...or compromised only with the [district] court's approval." The Rule requires the district court to "direct notice in a reasonable manner" to class members and make a "finding that [the settlement] is fair, reasonable, and adequate." Thus, "the role of a court reviewing the proposed settlement of a class action under Fed. R. Civ. P. 23(e) is to assure that the procedures

⁸³ See Lidoderm, 2017 WL 679367, at *13; Flonase, 274 F.R.D., at 137 ("because common questions predominate here, re-trying the case individually would leave all parties vulnerable to unfair inconsistencies"); Wellbutrin SR, 2008 WL 1946848, at *9 ("[i]n the instant case, denying certification would require each direct purchaser to file suit individually at the expense of judicial economy and litigation costs for each party"); TriCor, 252 F.R.D. at 231 ("[i]n the case at bar, denying certification would require each individual plaintiff to file suit individually, at the expense of judicial economy and litigation costs for each party"); K-Dur, 2008 WL 2699390, at *20-21 (finding that "resolution of these common issues in single action is a more efficient use of the Court's and the parties' resources than the alternative of potentially numerous additional individual actions"); Nifedipine, 246 F.R.D. at 371-72 (superiority established because "dozens of separate trials" featuring similar evidence would be inefficient); Ovcon, 246 F.R.D. at 313 (class action superior because manageability problems absent and "the Court is at a loss to understand how" several individual actions would promote efficiency); Premarin, 225 F.R.D. at 220 (superiority established where, inter alia, defendant would appear to benefit from resolving its liability in a single action).

⁸⁴ Manual for Complex Litigation (Fourth) §21.632 (West 2004).

⁸⁵ *Id*.

⁸⁶ Fed. R. Civ. P. 23(e)(1); *see also Winingear v. City of Norfolk*, No. 2:12CV560, 2014 WL 12526327, at *1 (E.D. Va. June 5, 2014) ("[Rule 23(e)] requires that class members receive notice of the settlement before the court approves it").

followed meet the requirements of the Rule and comport with due process and to examine the settlement for fairness and adequacy."⁸⁷ While the district court is to assure that fairness of the settlement, "there is a strong initial presumption that the compromise is fair and reasonable."⁸⁸

A hearing is neither necessary nor required under Fed. R. Civ. P. 23(e) at the preliminary approval stage. "In some cases," the Manual for Complex Litigation explains, this initial evaluation can be made on the basis of information already known, supplemented as necessary by briefs, motions, or informal presentations by parties." 89

In this circuit, the *Jiffy Lube* case provides district courts with a structure to evaluate both the fairness and the adequacy of class settlements. For fairness, the factors are "(1) the posture of the case at the time settlement was proposed; (2) the extent of discovery that had been conducted; (3) the circumstances surrounding the negotiations; and (4) the experience of counsel."90 For adequacy, *Jiffy Lube* directs the district court to consider: "(1) the relative strength of the plaintiffs' case on the merits; (2) the existence of any difficulties of proof or strong defenses the plaintiffs are likely to encounter if the case goes to trial; (3) the anticipated duration and expenses of additional litigation; (4) the solvency of the defendants and the likelihood of recovery on a litigated judgment; and (5) the degree of opposition to the settlement."91

The considerations here, under the Federal Rules and Fourth Circuit precedent, counsel in favor of preliminary approval of the Settlement.

⁸⁷ In re MicroStrategy, Inc. Sec. Litig., 148 F. Supp. 2d 654, 663 (E.D. Va. 2001).

⁸⁸ South Carolina Nat'l Bank v. Stone, 139 F.R.D. 335, 339 (D.S.C. 1991).

⁸⁹ Manual for Complex Litigation, § 21.632 at 382 (4th ed. 2005).

⁹⁰ In re Jiffy Lube Securities Litig., 927 F.2d 155, 159 (4th Cir. 1991); see also In re The Mills Corp. Sec. Litig., 265 F.R.D. 246, 254 (E.D. Va. 2009) (adopting Jiffy Lube factors).

1. Fairness

The posture of the case at the time settlement was proposed. Although the Settlement with Par was reached contemporaneously with the formal addition of Par as a defendant, before the Direct Purchaser Class Plaintiffs' added Par, they extensively investigated Par's involvement in the alleged scheme, before adding Par as a defendant. Discovery from the non-settling defendants was well underway with approximately two million pages of documents having been produced, including documents relating to the distribution agreement between Par and Glenmark. Direct Purchaser Class Plaintiffs' counsel engaged with counsel for Par on discovery issues well in advance of the Settlement. Par had already produced transactional data relating to the sale of the Par/Glenmark generic Zetia product. When Direct Purchaser Class Plaintiffs' counsel decided that they would seek leave to add Par as a defendant in this matter, an extensive round of negotiations, spanning a period of months, began between the parties. Those negotiations involved candid discussions about Par's financial circumstances, the delay in litigation and trial that might occur upon the addition of Par, the scope of document discovery Par would provide, including custodians and search term application, and Par's willingness and ability to provide one or more witnesses at trial of the claims against the remaining defendants.

The extent of discovery conducted. In addition to the discovery obtained before the execution of the Settlement, including documents relating to the Par/Glenmark distribution agreement and transactional data, the terms of the Settlement include additional expedited discovery from Par, including documents, data and deposition testimony produced on an expedited basis. But Class Counsel had already obtained extensive discovery from Glenmark concerning Par's distribution agreement before entering into the Settlement. From all defendants, by the time the Settlement was reached, Direct Purchaser Class Plaintiffs had

received more than two million pages of documents and were scheduling deposition dates of Merck and Glenmark current and former employees.

The circumstances surrounding the negotiations. Negotiations with Par began after

Direct Purchaser Class Plaintiffs provided Par's counsel with a draft amended complaint that
included Par as a defendant in the case. Par and Direct Purchaser Class Plaintiffs then engaged
in discussions, primarily related to the provision of discovery by Par, that might avoid the delay
in the litigation associated with adding Par as a defendant. Those negotiations spanned more
than two months, included numerous phone conversations involving at least seven counsel for
the Direct Purchaser Class Plaintiffs and three for Par at various times. Those discussions
eventually evolved into settlement negotiations, resulting in the Settlement, which was resolutely
negotiated by both sides and required numerous additional conferences to arrive at agreement.

The experience of counsel in the area of antitrust class action litigation. Counsel for the Direct Purchaser Class Plaintiffs have significant experience in delayed generic entry cases. Counsel are well versed in both the prosecution and settlement of this type of antitrust litigation having been involved in many such cases for over fifteen years, including trial of such claims on behalf of a certified class.⁹² The Direct Purchaser Settlement Class is composed primarily of

⁹² Some or all of the attorneys in this case have been counsel of record in dozens of pharmaceutical antitrust direct purchaser class actions in which the courts have granted final approval of settlements between the parties. *See, e.g., In re Celebrex,* No. 2:14-cv-361 (E.D. Va.); *In re Prograf Antitrust Litig.*, No. 11-md-2242 (D. Mass.) (final approval of settlement granted November 2, 2016); *Mylan Pharm., Inc. v. Warner Chilcott Pub. Ltd. Co.*, No. 12-cv-3824 (E.D. Pa.) (January 28, 2015); *In re Prandin Direct Purchaser Antitrust Litig.*, No. 10-cv-12141 (E.D. Mich.) (January 20, 2015); *In re Skelaxin (Metaxalone) Antitrust Litig.*, No. 12-cv-83 (E.D. Tenn.) (September 24, 2014); *In re Neurontin Antitrust Litig.*, No. 02-cv-1390 (D.N.J.) (July 31, 2014); *In re Flonase Antitrust Litig.*, No. 08-cv-3149 (E.D. Pa.) (June 14, 2013); *In re Wellbutrin XL Antitrust Litig.*, No. 08-cv-2431 (E.D. Pa.) (November 7, 2012); *Rochester Drug Co-Op. v. Braintree Labs., Inc.*, No. 07-cv-142 (D. Del.) (May 31, 2012); *In re DDAVP Antitrust Litig.*, No. 05-cv-2237 (S.D.N.Y.) (November 28, 2011); *In re Wellbutrin SR Antitrust Litig.*, No.

many of the same wholesaler entities that composes the classes in prior cases, and no member of the class has objected to the adequacy of class counsel in prior settlements. Direct Purchaser Class Plaintiffs' counsel have demonstrated throughout this litigation, and in similar antitrust litigation before this Court, 93 that they are experienced, capable, and have prosecuted this case with vigor and commitment.

2. Adequacy

The relative strength of the plaintiffs' case on the merits. The Direct Purchaser Class Plaintiffs believe that a jury could conclude that Par conspired with Glenmark and Merck to delay generic entry of Zetia.

The existence of any difficulties of proof or strong defenses the plaintiffs are likely to encounter if the case goes to trial. Despite confidence in their ability to prove Par's participation in the scheme to forestall generic entry, Par denies as much, and Direct Purchaser Class Plaintiffs acknowledge that there are hurdles to reaching a verdict and obtaining an enforceable judgment against Par. For one, proof of a conspiracy is challenging in any case, especially so in the antitrust context. As an alleged co-conspirator, Direct Purchaser Class Plaintiffs believe Par would not be able to recover as a direct purchaser under antitrust law by virtue of their purchases of generic Zetia. However, they anticipated Par and the non-settling defendants would raise the issue of Par's purchases to question Direct Purchaser Class Plaintiffs' standing as direct purchasers. Indeed, Merck recently filed a 12(b)(6) motion based, in part, on that very

⁰⁴⁻cv-5525 (E.D. Pa.) (November 21, 2011); *Meijer, Inc. v. Abbott Labs.*, No. C 07-5985 (N.D. Cal.) (August 11, 2011); *In re Nifedipine Antitrust Litig.*, MDL No. 1515 (D.D.C.) (January 31, 2011); *In re OxyContin Antitrust Litig.*, No. 04-md-1603 (S.D.N.Y.) (January 25, 2011); *In re TriCor Antitrust Litig.*, No. 05-cv-340 (D. Del.) (April 24, 2009); *Meijer, Inc. v. Warner Chilcott Holdings Co. III, Ltd.*, No. 05-cv-2195 (D.D.C.) (April 20, 2009).

⁹³ See generally In re Celebrex., C.A. No. 2:14-cv-361 (E.D. Va.).

argument.⁹⁴ Par's agreement as part of the Settlement covenanting not to bring or assert claims or counterclaims against Merck or Glenmark (to be clear, the direct purchaser plaintiffs think no such claims exist) arising under the Sherman or Clayton Acts undercuts that theory. Finally, as detailed below, given Par's financial status, Direct Purchaser Class Plaintiffs have concerns about whether any judgement against Par would ever be satisfied, or whether the risk of a potential bankruptcy might interfere with the progress toward trial of the claims against Merck and Glenmark.

The anticipated duration and expenses of additional litigation. The litigation began a year-and-a-half ago and the parties have already spent significant time and energy in discovery. Continuing to pursue claims against Par in the ordinary course of litigation could add substantial time to the discovery and trial schedule. Such delay is avoided by Par's agreement to the discovery called for under the Settlement on an expedited basis.

The solvency of the defendants and the likelihood of recovery on a litigated judgment.

Numerous news outlets have reported that Par's parent company, Endo International plc, is facing mounting – and potentially debilitating, company-ending – liabilities. As one *Bloomberg* article put it, Endo (and in turn, Par) is "beset by patient lawsuits, regulatory challenges, and looming debt payments." Endo's year-end 2018 report states in no uncertain terms that it may not be solvent at the end of this litigation: "We have been, continue to be and may be the subject of lawsuits, product liability claims, other significant legal proceedings, government investigations or product recalls for which we may be unable to obtain or maintain insurance

⁹⁴ See ECF No. 354, at *10-15.

⁹⁵ Bloomberg, Everything That Could Go Wrong for this Drugmaker Did, January 26, 2018, available at: https://www.bloomberg.com/news/articles/2018-01-26/everything-that-could-go-wrong-for-this-drugmaker-did.

adequate to cover potential liabilities." Endo's possible inability to pay a potential judgment in this litigation and potential bankruptcy were factors considered in reaching Settlement.

The degree of opposition to the settlement. If the Court preliminarily approves the Settlement and certifies the requested Direct Purchaser Settlement Class, notice will be provided to all class members by first class mail and be provided an opportunity to object to the Settlement, or opt-out if desired. Class Counsel does not anticipate any opposition.

C. The proposed form and manner of notice are appropriate.

Rule 23(e)(1) provides that "[t]he court must direct notice in a reasonable manner to all class members who would be bound by the propos[ed settlement]." The proposed forms of notice and notice program here fully comply with due process and Rule 23.

"All that the notice must do is fairly apprise the prospective members of the class of the terms of the proposed settlement so that class members may come to their own conclusions about whether the settlement serves their interests." The proposed Notice, Sobol Decl. Ex. 4, does just that. It describes the proposed Settlement and its legal significance, providing a description of the Direct Purchaser Settlement Class, the procedural status of the litigation, and the terms of the proposed Settlement. It also outlines the court approval process and advises class members of their rights under Rule 23, including the right to opt out of the Direct Purchaser Settlement Class, or to remain in the class but object to and be heard as to the proposed Settlement's reasonableness and fairness. The notice is substantially similar, in both form and substance, to

⁹⁶ See Endo Form 10-K filed with the Securities and Exchange Commission for the year ended 2018, available at:

https://www.sec.gov/Archives/edgar/data/1593034/000159303419000009/endp-12312018x10k.htm.

⁹⁷ In re Outer Banks Power Outage Litig., No. 4:17-cv-141, 2018 WL 2050141, at *6 (E.D.N.C. May 2, 2018) (citation and quotation omitted).

notices used in other direct purchaser generic delay cases and satisfies the notice requirements of Rule 23(e) and the due process requirements that must be met to bind each member of the class.

Rule 23(c)(2)(B) requires "the best notice practicable under the circumstances, including individual notice to all members who can be identified through reasonable effort." Here, because the Direct Purchaser Settlement Class is a finite group of businesses consisting of approximately seventy-one (71) members, identified from Par's and non-settling defendants' business records, individual direct mail notice is sufficient and practicable. ⁹⁸ Class Counsel will also post the notice and key litigation documents on a specially designated website. ⁹⁹

D. The Court should appoint RG/2 Claims as settlement administrator.

Direct Purchaser Class Plaintiffs request the Court appoint RG/2 Claims Administration ("RG/2 Claims") to oversee the administration of the Settlement, including disseminating notice to the class. Established in 2002, RG/2 is a full service class action notice and claims administrator, providing such services for a broad range of collective actions, including but not limited to antitrust, securities, consumer, and employment cases.¹⁰⁰

E. The proposed schedule is fair and should be approved.

Direct Purchaser Class Plaintiffs propose the following schedule for completing the approval process:

Dissemination of Notices to the Class in the form and manner proposed	Within 15 days of entry of the Order preliminarily approving the Settlement
Deadline for Class members to request exclusion from the Direct Purchaser Settlement Class or object to the Settlement	No later than 45 days from the date on the Settlement Notice

⁹⁸ *In re NeuStar, Inc. Sec. Litig.*, No. 1:14-cv-885, 2015 WL 5674798, at *12 (E.D. Va. Sept. 23, 2015) (approving notice by first class mail).

⁹⁹ See Sobol Decl., Ex. 4, at §2 ([Proposed] Notice).

¹⁰⁰ See Sobol Decl., Ex. 6 (Declaration of William W. Wikersham in Support of Direct Purchaser Class Notice Program).

Filing of Plaintiffs' motion for final approval of the Settlement	30 days before the date set for the Fairness Hearing
Fairness Hearing	To Be Determined By the Court

This proposal provides for sufficient time – 45 days – for class members to request exclusion from the Direct Purchaser Settlement Class or object to the Settlement. Any class member who timely objects to the Settlement may be heard at the fairness hearing.

F. The Court should stay all proceedings against Par in the MDL until the Settlement is finally approved.

A stay of proceedings in this litigation is both necessary and appropriate.

It is beyond dispute that "[t]his Court possesses the inherent authority to stay a matter in furtherance of judicial economy." Or that "[c]ourts routinely exercise this power and grant[] stays when a pending nationwide settlement could impact the claims." Indeed, courts have granted such stays under similar circumstances. 104

¹⁰¹ King Drug Co. of Florence, Inc. v. Cephalon, Inc., No. 06-cv-1797, ECF No. 948, at ¶¶ 4, 7 (E.D. Pa. Dec. 17, 2015) (30-day period approved in delayed generic competition case brought by direct purchasers); In re K-Dur Antitrust Litig., Order, Case No. 01-cv-1652, Doc. No. 887, at ¶¶ 2, 4 (D. N.J. Sept. 12, 2016) (same); DeJulius v. New Eng. Health Care Employees Pension Fund, 429 F.3d 935, 946 (10th Cir. 2005) (affirming a 32-day notice period and noting that "courts have found a notice scheme similar to the one in the instant case sufficient").

¹⁰² Wince v. Easterbrooke Cellular Corp., 681 F. Supp. 2d 688, 692 (N.D.W. Va. 2010) (citing Landis v. North American Co., 299 U.S. 248, 254–55, 57 (1936) ("The power to stay proceedings is incidental to the power inherent in every court to control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants. How this can best be done calls for the exercise of judgment, which must weigh competing interests and maintain an even balance.")).

¹⁰³ *Id.* (collecting cases); *see also In re Titanium Dioxide Antitrust Litig.*, No. CIV.A. RDB-10-0318, 2013 WL 5182093, at *6 (D. Md. Sept. 12, 2013) (ordering in an antitrust case that "[a]ll litigation proceedings shall remain stayed until this Court finally approves the Settlements and enters a final judgment").

¹⁰⁴ See, e.g., In re Vitamins Antitrust Litigation, No. MDL 1285, 2001 WL 856292, at *1-2 (D.D.C. July 25, 2001) (where settlement agreement required the settling class plaintiffs to move "for a formal stay of proceedings," the court granted the requested stay, recognizing it as "reasonable" and "routine[]"); see also Allen v. Dairy Farmers of Am., Inc., No. 5:09-cv-230,

The Court should likewise stay all proceedings against Par in this multi-district litigation except as may be necessary to effectuate the terms of the settlement agreement. The Direct Purchaser Class Plaintiffs have obtained discovery from Par that will enable not only the direct purchasers' case, but all cases in this litigation, to proceed expeditiously and within the confines of the schedule just entered by the Court. There is therefore no risk of prejudice to any other party. Indeed, a stay will permit Par to focus on meeting its expedited discovery obligations under the current schedule.

IV. CONCLUSION

For the foregoing reasons, the Direct Purchaser Class Plaintiffs respectfully request the Court grant this Motion. A proposed Preliminary Approval Order is submitted herewith for the Court's consideration. ¹⁰⁵

Dated: July 15, 2019

/s/ William H. Monroe, Jr

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²⁰¹¹ WL 1706778, *11 (D. Vt. May 4, 2011) (granting stay of all proceedings against settling defendant).

¹⁰⁵ Sobol Decl., Ex. 3.

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CERTIFICATE OF SERVICE

I hereby certify that on July 15, 2019, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send a notification of such filing (NEF) to all

counsel of record who have made a formal appearance.

Dated: July 15, 2019 /s/ William H. Monroe, Jr.

<u>/s/ William H. Monroe, Jr.</u> William H. Monroe, Jr. (VSB No. 27441)